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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/657,446	09/08/2000	David E. Edgren	ARC 2762C1	1540

7590 07/15/2003

Vandana Date
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EXAMINER
FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
1615	20

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/657,446	EDGREN ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04/15/03* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46,48,49 and 51-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46,48,49 and 51-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time and Notice of Appeal filed 10/15/02; request for extension of time, request for continued examination under 37 CFR 1.114 and amendment C filed 04/15/03. Claims 46, 48, 49 and 51-60 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 04/15/03 has been entered.

Claim Rejections - 35 USC § 102

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 46, 48, 49, 51-58 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Kjornaes et al. (US 4,713,248).

Kjornaes discloses a pharmaceutical controlled release dosage form comprising individually coated units that contain active substances. The coat comprises outer and inner film layers. The outer film layer of METHOCEL is coated onto the inner film layer of EUDRAGIT and METHOCEL. The film forming substances are selected from ethylcellulose, hydroxypropylmethylcellulosephthalate and cellulose acetate phthalate. Hydroxypropylcellulose, carboxymethylcellulose, methylcellulose, propylcellulose, hydroxyethylcellulose, hydroxymethylcellulose and hydroxypropylmethylcellulose are few examples of polymeric substances incorporated in the inner layer. Kjornaes teaches oral administration (column 6, lines

20-29). See abstract, column 2, line 38 to column 3, line 59, column 5, lines 13-33 and columns 7-12. The method claimed in the application is a broad administration of the claimed composition and the scope of the claims read on the teachings of Kjornaes. The dosage of Kjornaes would be capable of the release profile recited in claims 55-58 of the application since the dosage form of Kjornaes reads on the claimed dosage form. The teachings of Kjornaes meet the limitations of the claims.

Applicants argue that the film layers of Kjorneas are not semipermeable. However, applicants formulation broadly read on osmotic dosage forms and there is no claim to any specific membrane material that would make the second membrane of applicants dosage form semipermeable and the film of the prior art not. Semipermeable nature of the membrane is a property of the membrane and the film of the Kjorneas would be inherently semipermeable and would respond to osmotic pressure changes.

4. Claims 46, 48, 49, 51-58 and 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (US 5,558,879).

Chen discloses a controlled release dosage form comprising a core of medicament and pharmaceutically acceptable excipients and polymeric binders and osmotic agents. The core is coated with a dual membrane coating where the dual membrane consists of first inner coating layer and a second outer coating layer. See abstract. A 24-hour therapeutic blood level is achievable with this dosage form (column 3, lines 59-64). The inner coating layer consists of plasticized water insoluble pharmaceutically acceptable polymer and a pharmaceutically acceptable water-soluble polymer; the second outer coating consists of a medicament and water-soluble polymer (abstract). Water-insoluble polymers applicable in Chen are cellulose esters, cellulose ethers, cellulose acylate, cellulose acetate, cellulose diacetate, ethylcellulose and cellulose ethyl ether. Hydroxymethyl

cellulose, hydroxypropyl cellulose or cellulose may be combined with the water insoluble polymer to modify the permeability of the membrane coat around the core (column 5, lines 1-20 and column 6, lines 6-56). The application does not exclude medicine from the outer membrane coat layer. The dosage of Chen would be capable of the release profile recited in claims 55-58 of the application since the dosage form of Chen reads on the claimed dosage form. The teachings of Chen meet the limitations of the claims.

Applicants argue that Chen does not teach that the membrane is capable of responding to changes in osmotic pressure. However, response to changes in osmotic pressure is a property of the membrane and it is respectfully noted that no specific membrane material is claimed that would make applicants' membrane semipermeable and the prior art's not. The instant claims are broadly directed to osmotic dosage forms.

5. Claims 46, 48, 49 and 51-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Bartoo et al. (US 4,743,248).

Bartoo teaches an osmotic dosage form comprising an outside wall and an inside wall (abstract). The outside wall comprises semipermeable polymers where the semipermeable polymers are cellulose esters, cellulose ethers, cellulose acylate, cellulose acetate and cellulose diacetate and triacetate (column 3, line 54 to column 4 line 5). The inside wall comprises polymeric formulation that is responsive to environmental changes such as pH (column 4, lines 6-9). The internal compartment comprises beneficial agents or active drugs and the dosage form also has an expandable layer (column 4, lines 47-68 and column 7, line 6). In example 1, the cores are coated with an inside wall forming composition comprising hydroxypropylmethylcellulose phthalate, cellulose acetate, sorbitol and polyethylene glycol; and the second outside semipermeable wall is coated onto to the inside wall. The scope of the claims in the application reads broadly on a

conventional osmotic dosage form and reads on Bartoo. The dosage of Bartoo would be capable of the release profile recited in claims 55-58 of the application since the dosage form of Bartoo reads on the claimed dosage from. The claimed method is a broad administration of the claimed composition and Bartoo's dosage form is administered to animals. Thus, Bartoo anticipates the claims.

Applicants argue that Bartoo's membranes do not respond to changes in osmotic pressure. However, the scope of the instant claims is such that any membrane would be responsive to changes in osmotic pressure. The claims broadly recite first and second membrane and response of the membrane to changes in osmotic pressure is a property of the membrane.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara MBFubara
Patent Examiner
Tech. Center 1600
July 10, 2003